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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,633	04/15/2004	Thomas D. Willis	AFMX-P02-201	1327

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EXAMINER

STAPLES, MARK

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/826,633

Applicant(s)

WILLIS ET AL.

Examiner

Mark Staples

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-71 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 48-71 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04/02/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/9/05 & 12/27/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Priority

1. The first paragraph of the specification should be updated to reflect that Application 09/999,362 has issued as U.S. Patent No. 6,858,412.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title should reflect that the claimed invention is a multiplex method for detecting and amplifying target DNA. Also, the claims are not drawn to "genomic" DNA and thus this adjective should be deleted.
4. The abstract of the disclosure is objected to because genotyping is not the claimed invention. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 48-71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 48 and 69 are drawn to "one or more target sequences" in line 1 of each of these base claims which reads on any sequence, including amino acid sequences and nucleic acid sequences. However, the method steps in claims 48-71 appear to be drawn only to nucleic acid sequences. It may be that one of the phrases "one or more nucleic acid target sequences" or "one or more DNA target sequences" or similar is intended.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 48-54, 56, 57, 60-62, and 64-71 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-47 of U.S. Patent No. 6,858,412. Although the conflicting claims are not identical, they are not patentably distinct from each other because the critical elements of claims 38-71 of the instant application of Willis et al. are found in claims 1-47 of U.S. Patent No. 6,858,412 of Willis et al.

The critical elements of claim 48 are found in claims 1, 20, 26, and 40 of U.S. Patent No. 6,858,412. Forming circular probes, cleaving the probes, amplifying the cleaved probes and detecting amplicons is found in claims 1, 20, 26, and 40 of U.S. Patent No. 6,858,412.

The critical element of claim 49, digesting said precircle, is found in claim 12 of U.S. Patent No. 6,858,412.

The critical elements of claims 50 and 51, barcode sequence, detection and hybridization, are found in claims 20, 25, 26, and 33 of U.S. Patent No. 6,858,412.

The critical elements of claims 53 and 54, second universal primer site and making of amplicons thereby, are found in claims 4 and 5 of U.S. Patent No. 6,858,412.

The critical element of claim 56 and 57, hybridizing a label probe which can be a directly detected label, is found in claim 17 of U.S. Patent No. 6,858,412.

The critical element of claim 60, a gap domain, is found in claims 6, 7, and 8 of U.S. Patent No. 6,858,412.

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The critical element of claim 61, a second universal primer site with a cleavage site between the first and second universal primer sites, is found in claims 23 and 24 of U.S. Patent No. 6,858,412.

The critical element of claim 62, making amplicons with a first universal primer and second universal primer complementary to the second universal primer site, is found in claims 23 and 24 of U.S. Patent No. 6,858,412 where a primer, which can be the second universal primer, can be complementary to the second universal primer site.

The critical element of claim 64, a second universal primer site with a cleavage site between the first and second universal primer sites, is found in claims 23 and 24 of U.S. Patent No. 6,858,412.

The critical elements of claim 64, 65, and 67, ligating a gap domain and by use of ligase, is found in claims 1, 20, 26, 31, 34, especially 38, and 40 of U.S. Patent No. 6,858,412 where ligase is used to perform the ligating.

The critical element of claim 66, a gap between 1 and 500 nucleotides, is found in claim 10 of U.S. Patent No. 6,858,412 which is drawn on a gap of between 1 to 1000 nucleotides which includes the range of 1 to 500.

The critical elements of claim 69-71, amplifying cleaved probes and with polymerase chain reaction and with a second universal primer, are found in claims 37 and 38 in view of claim 4 respectively of U.S. Patent No. 6,858,412.

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7. Claims 55, 63, 58, and 59 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-47 of U.S. Patent No. 6,858,412 of Wills et al. in view of Speel (September 1999).

Claims 1-47 of U.S. Patent No. 6,858,412 are drawn as noted above.

Claims 1-47 of U.S. Patent No. 6,858,412 are not drawn to an exonuclease, hapten, or biotin of claims 55, 63, 58, and 59 of the instant application.

Regarding claims 55 and 63, Speel teaches exonuclease (see Table 2).

Regarding claims 58 and 59, Speel teaches the use of a hapten and of biotin (entire reference, especially Table 1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply Speel's exonuclease, hapten, and biotin to the method claim to U.S. Patent No. 6,858,412 in order to successfully detect and amplify one or more target nucleic acid sequences. The motivation to do so is provided by Speel who teaches that use of haptens and biotin leads to successful detection and teach that the nucleic acid sequences can be treated by exonuclease during amplification. Thus, it would have been *prima facie* obvious to apply Speel's teachings to U.S. Patent No. 6,858,412 in order to maximize detection and amplification of nucleic acid sequences.

8. Claims 48-71 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 16 of copending Application No. 11,152,460 in view of Speel (September 1999). Claims 1-7

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and 16 of copending Application No. 11,152,460 of Willis et al. are drawn to methods determining a genotype which are species anticipating genus methods of determining one or more target sequences of claims 48-71 of the instant application of Willis et al.

Claims 1-7 and 16 of copending Application No. 11,152,460 are not drawn to methods using circular probes.

Speel teaches as noted above and teaches methods using circular probes.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply circular probes of Speel to claims 1-7 and 16 of copending Application No. 11,152,460 in order to successfully detect one or more target nucleic acid sequences of the instant application. The motivation to do so is provided by Speel who teaches that use of circular probes leads to successful detection of nucleic acid sequences (see p. 90, last sentence of 2nd column for "Padlock probes are oligonucleotides that can be ligated into circles").

Thus, it would have been *prima facie* obvious to apply the teachings of Speel to copending Application No. 11,152,460 in order to maximize detection of genotypes and other target sequences.

This is a provisional obviousness-type double patenting rejection.

9. Claims 48-71 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 48-72 of copending Application No. 11,335,196 in view of Speel (September 1999). Claims 48-72 of copending Application No. 11,152,460 of Willis et al. are drawn to methods

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determining the identity of a nucleotide which are species anticipating genus methods of determining one or more target sequences of claims 48-71 of the instant application by Willis et al.

Claims 48-72 of copending Application No. 11,335,196 are not drawn to methods using circular probes.

Speel teaches as noted above and teaches methods using circular probes.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply circular probes of Speel to claims 48-72 of copending Application No. 11,335,196 in order to successfully detect the identity of a nucleotide or other target sequences of the instant application. The motivation to do so is provided by Speel who teach that use of circular probes of leads to successful detection of nucleic acid. Thus, it would have been *prima facie* obvious to apply the teachings of Speel to copending Application No. 11,335,196 in order to maximize detection of nucleotides and other target sequences.

This is a provisional obviousness-type double patenting rejection.

10. Claims 48-71 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 11,375,818 in view of Speel (September 1999). While claims 1-14 of copending Application No. 11,375,818 of Willis et al. are drawn to methods of synthesizing polynucleotides, they also are drawn within the method to use of genus

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primers and probes which render obvious the methods of detecting nucleic acids with the circular probes of claims 48-71 of the instant application by Willis et al.

Claims 1-14 of copending Application No. 11,375,818 are not drawn to methods using circular probes.

Speel teaches as noted above and teaches methods using circular probes.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply circular probes of Speel to claims 1-14 of copending Application No. 11,375,818 in order to successfully detect target sequences of the instant application. The motivation to do so is provided by Speel who teach that use of circular probes of leads to successful detection of nucleic acid. Thus, it would have been *prima facie* obvious to apply the teachings of Speel to copending Application No. 11,375,818 in order to maximize detection of target sequences.

This is a provisional obviousness-type double patenting rejection.

Conclusion

11. Claims 48-71 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 6:00 p.m.

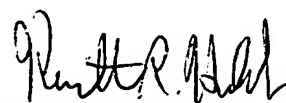
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Staples
Examiner
Art Unit 1637
September 12, 2006

ms


KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER
9/14/06